

1.2 IN THE CLAIMS

Please amend the claims to read as follows:

1. (Currently Amended) A method of preparing aggregates of porcine pancreatic islets and porcine Sertoli cells capable upon implantation into a recipient, of producing insulin *in vivo*, including or comprising the steps of :
 - 1) ~~isolation of~~isolating porcine islet cells from the pancreas of donor piglets,
 - 2) ~~isolation of~~isolating porcine Sertoli cells from the testes of donor piglets,
 - 3) ~~culturing the islet cells together with the Sertoli cells,~~
 - 4) ~~formation of the aggregates.~~
 - 3) culturing the Sertoli cells for at least 1 day;
 - 4) adding the isolated porcine islet cells to the cultured Sertoli cells at a predetermined ratio;
 - 5) co-culturing the islet cells and Sertoli cells for at least 1 day;
 - 6) scraping the Sertoli cell layer over the islets to form aggregates; and
 - 7) culturing the aggregates for up to 24 hours.
2. (Currently Amended) A~~The~~The method of claim 1, wherein said aggregate is a combination of islet:sertoli cells in a ~~predetermining~~predetermined ratio ~~of~~ from about 1:20,000 to about 1:100.
3. (Currently Amended) A~~The~~The method of claim 2, wherein said ratio is between about 1:2,000 ~~to and about~~ 1:4,000.
4. (Currently Amended) A~~The~~The method of ~~any one of the preceding claims~~claim 1, wherein

- said co-culturing step 5) is over a time period of from between about 3 to and about 7 days.
5. (Currently Amended) ~~A~~The method of claim 4, wherein ~~the~~said time period is ~~for~~about 5 days.
 6. (Currently Amended) ~~A~~The method of ~~any one of the preceding claims~~claim 1, wherein said isolation of the islets is followed by purification of the islets.
 7. (Currently Amended) ~~A~~The method of claim 6, wherein the isolation and purification of the islets together comprise ~~or include~~ the steps of:
 - a) surgical removal;
 - b) collagenase digestion; and
 - c) washing and culturing of the islets.
 8. (Currently Amended) ~~A~~The method of claim 7, wherein said collagenase digestion involves Liberase H and Xylocaine.
 9. (Currently Amended) ~~A~~The method of ~~any one of the preceding claims~~claim 1, wherein said isolation of the Sertoli cells is followed by purification of the Sertoli cells.
 10. (Currently Amended) ~~A~~The method of claim 9, wherein said isolation and purification of the Sertoli cells together comprise or include the steps of:
 - a) surgical removal,
 - b) digestion with trypsin[,]and Dnase; and
 - c) washing and culturing of ~~the~~said cells.

11. (Currently Amended) ~~A method of any one of the preceding claims~~The method of claim 1, wherein the method further includes the additional step of:

[5]8) virological and microbiological testing ~~and/or~~ monitoring of ~~the~~said aggregates ~~and/or~~ components thereof.
12. (Currently Amended) ~~A method of any one of the preceding claims~~The method of claim 1, wherein the method additionally or alternatively includes a pre-step before step 1) that comprises ~~of~~ virological monitoring ~~and/or~~ testing of one or both of ~~the~~said islets ~~or~~ said Sertoli cells.
13. (Currently Amended) ~~A method of any one of the preceding claims~~The method of claim 1, wherein the method additionally or alternatively includes a pre-step before step 1) of virological monitoring ~~and/or~~ testing of the piglet donors.
14. (Currently Amended) ~~A method of any one of the preceding claims~~The method of claim 1, wherein said islets and Sertoli cells are derived from the same herd or from the same donor piglet(s).
15. (Currently Amended) ~~A~~The method of claim 14, wherein ~~the~~ said donor piglet(s) are about one week old donors.
16. (Currently Amended) ~~A method of any one of the preceding claims~~The method of claim 14, wherein ~~the~~said donor piglet(s) are monitored ~~and/or~~ tested for infectious agents.
17. (Currently Amended) ~~A method of any one of the preceding claims~~The method of claim 14, wherein said donor piglet(s) are from a New Zealand pig herd.
18. (Currently Amended) ~~A method of any one of the preceding claims~~The method of claim 1, wherein the step of the formation of the aggregate additionally or alternatively ~~includes~~comprises the preservation of the original characteristics ~~and/or~~ native structure

of the islets.

19. (Currently Amended) An aggregate of porcine islets with Sertoli cells prepared substantially according to ~~a method of any one of claims 1 to 18~~ the method of claim 1.
20. (Currently Amended) A method of treating a patient suffering from diabetes mellitus comprising ~~or including~~ the steps of:
 - 1) preparing one or more aggregates of porcine islets with Sertoli cells ~~prepared substantially according to a method of any one of claims 1 to 18~~ the method of claim 1; and
 - 2) implanting or otherwise administering one or more of said aggregates to ~~the~~ said patient.
21. (Currently Amended) ~~A~~ The method of claim 20, wherein said step of implanting or administering the aggregate may be by:
 - (a) encapsulation of the aggregate in a suitable biocompatible material;
 - (b) confinement into a suitable device;
~~matrix preparations including preparation of gelatin, collagen, and natural carbohydrate polymers.~~
~~plasma thrombin clot autologous plasma clots produced with allogeneic thrombin.~~
 - (c) inclusion in a matrix that comprises gelatin, collagen, or natural carbohydrate polymers; or
 - (d) inclusion in a plasma thrombin clot or an autologous plasma clot produced with allogeneic thrombin.
22. (Currently Amended) ~~A~~ The method of claim 21, wherein ~~the~~ said biocompatible

material iscomprises a suitable alginate.

23. (Currently Amended) ~~A~~The method of ~~any one of claims 21 to 22~~claim 21, wherein the said suitable device is a vascularized tube.

24. (Currently Amended) A device for implantation into a recipient suffering from diabetes mellitus, wherein said ~~the device incorporating aggregates of porcine pancreatic islets and porcine Sertoli cells, the aggregates being, or possessing the characteristics of,~~comprises the aggregates of claim 19 an aggregate of porcine islets with Sertoli cells prepared substantially according to the method of claim 1.

25. (Currently Amended) ~~A~~The device of claim 24, wherein said device incorporating the aggregates may be one of :

[-](a) a suitable biocompatible material as a capsule;

[-](b) a vascularized tube;

~~— a matrix preparation including preparation of gelatin, collagen, and natural carbohydrate polymers;~~

~~— a plasma thrombin clot autologous plasma clots produced with allogeneic thrombin.~~

(c) a matrix preparation comprising gelatin, collagen, or natural carbohydrate polymers; or

(d) a plasma thrombin clot or an autologous plasma clot produced with allogeneic thrombin.

26. (Currently Amended) ~~A~~The device of claim 25, wherein said biocompatible material iscomprises a suitable alginate.

27-28. (Canceled)